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EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,777	TOCCHINI-VALENTINI ET AL.	
	Examiner	Art Unit	
	DANA SHIN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-23* is/are pending in the application.

4a) Of the above claim(s) *18-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on January 4, 2008.

Currently, claims 1 and 4-17 are under examination on the merits.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claim Rejections – Double Patenting

Claims 1 and 4-17 remain rejected under 35 U.S.C. 101, as failing claiming the same invention as that of claims 1-17 of copending Application No. 10/296,574 for the reasons of record as set forth in the Office action mailed on July 5, 2007 and for the reasons stated below.

Applicant did not provide any arguments addressing this rejection. Hence, this rejection is maintained.

Claim Rejections - 35 USC § 103

Claims 1 and 4-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fabbri et al. (citation of record) in view of Santoro et al. for the reasons of record as set forth in the Office action mailed on July 5, 2007 and for the reasons stated below.

Applicant's arguments filed on January 4, 2008 have been fully considered but they are not persuasive. Applicant argues that the teachings of Fabbri et al. pertain to processing pre-tRNA containing a BHB motif and they do not disclose trans-formed BHB motifs. Although applicant is correct that Fabbri et al. do not disclose trans-formed BHB motifs, they do teach that both eukaryal and archaeal endonucleases have the ability and potential to cleave any RNA substrates having a BHB motif. See the last paragraph on page 285, wherein Fabbri et al. teach that "when a substrate contains the whole BHB motif, the conserved spatial positioning of the two active sties of the eukaryal and archaeal endonucleases allows for cleavage at both ends of the intron", which demonstrates a conserved, common mechanism for recognition for tRNAs and "other RNA substrates". This teaching indicates that both eukaryal and archaeal endonucleases can cleave a universal substrate containing the whole BHB motif. Furthermore, Fabbri et al. teach that both archaeal and eukaryotic tRNA endonucleases recognize and cleave the RNA substrate at the U/A (3' cleavage site) and G/A (5' cleavage site) within the BHB motif. See Figures 1 and 2. Although Fabbri et al. do not teach inducing a BHB motif in a target RNA by hybridizing the target RNA with an oligonucleotide designed to form a BHB motif, known as a trans-formed BHB, Santoro et al. teach the principle that one of ordinary skill in the art can induce target RNA cleavage by introducing an appropriate oligonucleotide sequence.

With regard to the teachings of Santoro et al., applicant argues that the DNAzymes of Santoro et al. are nucleotides and the eukaryal endonucleases are amino acids, and therefore, one of ordinary skill in the art cannot find any useful teaching so as to be motivated to make the claimed invention. It appears that applicant has misinterpreted the intent of using the teachings of Santoro et al. It is true that Santoro et al. taught DNAzymes; however, the essence of the teachings of Santoro et al. in the context of the claimed invention is that they taught target RNA cleavage by artificially inducing the hybridization via an oligonucleotide, which is the claimed step of the instantly claimed invention. That is, one of ordinary skill in the art knowledgeable of the target RNA cleavage mechanisms of DNAzymes would have known that one can trigger target RNA cleavage by introducing an oligonucleotide that has the appropriate motifs (e.g., "8-17" or "10-23") and nucleotides (T or A or G). See Figure 2 of Santoro et al. Hence, one skilled in the art knowledgeable of the teachings of Fabbri et al. (especially, the last paragraph of page 285) and those of Santoro et al. would have been motivated to design an oligonucleotide which can form an BHB motif with the target RNA so as to allow the target RNA cleavage. In other words, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the conserved, common mechanism for recognizing non-tRNA RNA substrates which contain the whole BHB motif having the two active sites (U/A, the 3' cleavage site and G/A, the 5' cleavage site) of Fabbri et al. to cleave a desired target mRNA molecule by artificially inducing the target mRNA molecule to contain the whole BHB motif via an introduction of an oligonucleotide, which would ultimately allow an eukaryal endonuclease to cleave the target mRNA molecule. Accordingly, this rejection is maintained.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Claims 12 and 14 recite a "second" RNA molecule. The recitation of the "second" RNA molecule inherently indicates the presence of a previous RNA molecule (e.g., "first" RNA molecule), which is not recited in the claims. Hence, the claimed invention of claims 12 and 14 is indefinite since it appears that an essential element is missing.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are currently amended to recite limitations that were not recited previously. Applicant has not pointed out where the amended claims is supported, nor does there appear to be a written description of the claim limitation "one bulge of the bulge-helix-bulge has a guanine/adenine dinucleotide and the other bulge of the bulge-helix-bulge has either an uracil/adenine dinucleotide or a thymine/adenine dinucleotide" in the application as filed. Accordingly, the claim limitation is considered to introduce new matter which is not adequately described in the application as originally filed.

Conclusion

No claim is allowed.

This application contains claims 18-23 drawn to an invention nonelected without traverse in the reply filed on March 8, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner, Art Unit 1635